DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 10 2002

Joanne Robinett
Director, Regulatory Affairs
Consumer Care Division
Bayer Corporation
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Re: Docket No. 76N-052N/CP18

Dear Ms. Robinett:

This letter responds to your citizen petition dated March 20, 2002, requesting that the Food and Drug Administration (FDA) amend the Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Nasal Decongestant Drug Products published August 23, 1994 (59 FR 43386). The amendment would provide for recognition of phenylephrine bitartrate as a generally regarded as safe and effective (GRAS/E) nasal decongestant active ingredient to use in single or multiple ingredient cold/cough/allergy products when delivered via an effervescent formulation.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible, given the numerous demands on the Agency's resources.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research